

REMARKS

In the Office Action dated September 1, 2010, claim 22 was examined while claims 1-21 and 23-39 remain withdrawn from further consideration in view of Applicant's previous election in response to the Restriction Requirement of August 25, 2006. In the current Office Action, the Examiner has rejected claim 22, and has made the rejection non-final. In response, Applicant presents the following arguments, and respectfully requests reconsideration of pending claim 22.

In the Office Action, claim 22 is rejected under 35 U.S.C. §102(b) as being anticipated by DeLuca et al US 5,843,928. The Examiner indicates that the '928 reference claims a class of 2-alkylidene-19-nor-vitamin D compounds (see claim 1), and claim 8 sets forth a specific side chain which is identical to the side chain of the vitamin D compound of present claim 22. Further, the Examiner states that the presently claimed compound of claim 22 is exemplified in claim 8 of the '928 reference when Y₁, Y₂, R₆ and R₈ are all hydrogen. Specifically, the Examiner states in the Office Action of January 12, 2010 that:

"It is clear from the disclosure of DeLuca et al that hydrogen is the preferred substituent of Y₁, Y₂, R₆ and R₈ since in both Schemes I and II in columns 21-26 of DeLuca et al the end products are exemplified with hydrogen being the substituent of Y₁, Y₂, R₆ and R₈."

As a result, the Examiner believes that the subgenus defined by claim 8 is more limited than the broad generic formula of claim 1 with the result that "very few combinations can be obtained." Thus, because of the limited genus set forth in claim 8 of the '928 reference, the Examiner alleges that one of ordinary skill in the art would "at once envisage" Applicant's compound of claim 22 by selecting hydrogen for the various substituents Y₁, Y₂, R₆ and R₈ from the list of alternatives given in a combination of claims 1 and 8 of the '928 reference.

In response to the Office Action of January 12, 2010, Applicant argued that (1) the compound of present claim 22 is not specifically disclosed in the '928 reference because it is neither named nor specifically illustrated via a chemical structure in the '928 reference; and (2) although Schemes I and II show an end product with hydrogen for Y₁, Y₂, R₆ and R₈, this is not

evidence hydrogen is the preferred substituent, but instead only that hydrogen was inserted to synthesize the compound being claimed.

In response to the argument filed July 12, 2010, the Examiner now takes the position that, because the end products of Schemes I and II are actually claimed in DeLuca et al '928, this evidences that hydrogen is the preferred substituent for Y₁, Y₂, R₆ and R₈. Specifically, the Examiner states in the present Office Action of September 1, 2010 that:

"This argument is not found persuasive because the compounds in DeLuca et al disclosed as the end products of both Schemes I and II in columns 21-26 are also the specific compounds claimed in claims 12 and 13 of DeLuca et al and having hydrogen as the substituent of Y₁, Y₂, R₆ and R₈. Thus, as previously argued, it is clear from the disclosure of DeLuca et al and the claims of DeLuca et al that hydrogen is the preferred substituent of Y₁, Y₂, R₆ and R₈."

The Examiner thus once again concludes that the compound of present claim 22 is anticipated by the '928 reference because one of ordinary skill in the art would be able to "at once envisage" the specific compound of instant claim 22 by selecting hydrogen from the various substituents Y₁, Y₂, R₆ and R₈.

Applicant, however, once again respectfully disagrees for the following reasons.

With all due respect, Applicant believes the Examiner is utilizing hindsight when rejecting the claims for anticipation based on the '928 patent. Applicant believes the proper rejection should be a §103(a) rejection for obviousness, but not a §102(b) rejection for anticipation.

The Examiner states that because claim 8 of the '928 reference illustrates the same side chain as being claimed by Applicant in present claim 22, it is a "preferred" side chain. However, the side chain illustrated in claim 8 of the '928 patent is not the only side chain illustrated and claimed. For example, claim 2 of the '928 patent illustrates a side chain which also must be considered as a "preferred" side chain in accordance with the Examiner's logic. Likewise, claims 3-7 and 9-11 also illustrate and claim various side chains which, in accordance with the Examiner's logic, should also be considered "preferred" side chains because these side chains are actually claimed in the '928 patent. Since the side chains of claims 2-11 are all "preferred" as

alleged by the Examiner, the list of "preferred" compounds has suddenly grown significantly, and the Examiner cannot state that the subgenus defined by the side chain of claim 8 is the only preferred subgenus. Also, the Examiner cannot point to anything in the '928 reference which tells one skilled in the art to choose the side chain of claim 8 as opposed to the side chains of claims 2-7 or 9-11. Thus, without the use of hindsight, how did the Examiner pick the side chain of claim 8 of the '928 reference to be the "preferred" side chain instead of one of the side chains of claims 2-7 or 9-11?

The Examiner states that because the end products synthesized in the '928 patent are actually claimed in claims 12 and 13 thereof, and since those end products have hydrogen for the substituents Y₁, Y₂, R₆ and R₈, this means that hydrogen is the "preferred" substituent for Y₁, Y₂, R₆ and R₈. However, the Examiner cites no support for that position. Clearly, Applicant did not specifically state that hydrogen is the preferred substituent for Y₁, Y₂, R₆, and R₈. Instead, Applicant suggests turning to what is, in fact, actually stated in the description of the '928 patent, rather than making conclusions without any specific support in the description of the '928 patent. More specifically, referring to column 6, lines 53-55 of the '928 reference, it is stated:

"Specific and preferred examples of the 2-alkylidene-compounds of structure I when the side chain is unsaturated are:" (emphasis added)

The description then lists 12 different "2-alkylidene-compounds" with an unsaturated side chain. The Examiner should note that all of the compounds listed thereafter in columns 6 and 7 are 1 α ,25-dihydroxy compounds and in addition all of the compounds are referred to as "2-alkylidene" compounds, not 2-methylene compounds. Thus, none of the compounds have the side chain of claim 8, but are referred to as "preferred examples."

Also referring the Examiner to column 7, lines 14-16 of the '928 reference, it is stated therein that:

"Specific and preferred examples of the 2-alkylidene-compounds of structure I when the side chain is saturated are:" (emphasis added)

The description then goes on to list 12 different compounds which all have saturated side chains. Again, it should be noted that all of the listed compounds are 1 α ,25-dihydroxy compounds, which are not the side chain of claim 8, and further, all of the compounds listed are again referred to as "2-alkylidene" compounds, not 2-methylene compounds.

The significance of referring to the "preferred" examples found in columns 6 and 7 of the '928 reference as "2-alkylidene-compounds" can be seen from the description found at column 6, lines 41-53. This paragraph states as follows:

"In the following lists of compounds, the particular alkylidene substituent attached at the carbon 2 position should be added to the nomenclature. For example, if a methylene group is the alkylidene substituent, the term "2-methylene" should precede [sic] each of the named compounds. If an ethylene group is the alkylidene substituent, the term "2-ethylene" should precede [sic] each of the named compounds, and so on. In addition, if the methyl group attached at the carbon 20 position is in its epi or unnatural configuration, the term "20(S)" or "20-epi" should be included in each of the following named compounds. The named compounds could also be of the vitamin D₂ type if desired."

The above quotation instructs one skilled in the art to add the appropriate alkylidene substituent desired at the carbon 2 position to the nomenclature of the compounds listed in columns 6 and 7. In other words, the term "2-methylene" or the term "2-ethylene" or the term "2-propylene" or the term "2-butylene" and the like should be added to each of the named compounds at columns 6 and 7 as "preferred" compounds. The Examiner should note that the term "alkylidene" is defined at column 3, line 32 as =CR²R³, and the substituents R² and R³ may each independently be selected from deuterium, deuterioalkyl, hydrogen, fluoro, trifluoromethyl and C₁₋₅ alkyl which may be straight-chain or branched and optionally bear a hydroxy or protected hydroxy substituent. Thus, the compounds in columns 6 and 7 of the '928 reference which are listed as "preferred examples," when added to the "preferred" side chains illustrated in claims 2-11, lists a very large genus which has exponentially grown from the "very few combinations" alleged by the Examiner, and is not a genus or subgenus of limited scope, as alleged by the Examiner.

Finally, Applicant refers the Examiner to column 8, lines 15-18 wherein it states:

"In the structures II, III and IV groups Y₁ and Y₂ and R represent groups defined above; Y₁ and Y₂ are preferably hydroxy-protecting groups..." (emphasis added)

Thus, the description of the '928 reference states that Y₁ and Y₂ are "preferably" hydroxy-protecting groups. Hydroxy-protecting groups are defined at column 5, line 64 through column 6, line 21 and generally include silyl groups, alkoxyalkyl groups, acyl groups, or alkoxycarbonyl groups. These compounds may sometimes be referred to as "prodrugs" because they are known to be converted to the active ingredient, or end product, in vivo. Thus, persons skilled in the art would just as likely find the prodrug to be the preferred compound as the end product per se. Regardless, the description of the '928 patent states that Y₁ and Y₂ are "preferably" hydroxy-protecting groups and as defined at column 5, line 64 through column 6, line 21, includes an extremely large genus of compounds. Again, the list of "preferred" compounds set forth in the '928 reference has grown exponentially and the Examiner cannot consider that just because the side chain illustrated in claim 8 was actually claimed means that such side chain is the one and only "preferred" side chain. Thus, the description of the '928 reference itself directs one skilled in the art to an extremely broad "preferred" genus of compounds.

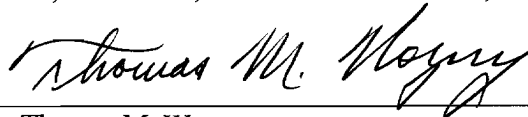
As a result, without the benefit of hindsight, one skilled in the art would not have "at once envisaged" the structure of present claim 22 from what is taught and described in the '928 reference. Accordingly, Applicant requests the Examiner withdraw the rejection of claim 22 under 35 U.S.C. §102(b) based upon the '928 reference, and instead consider a rejection under 35 U.S.C. §103(a) based upon the '928 reference. Upon receipt of such a rejection, Applicant will present evidence of unobviousness or unexpected advantageous properties of the presently claimed compound versus those taught and described in the '928 reference.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By



Thomas M. Wozny
Reg. No. 28,922

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Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770